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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,339	05/11/2005	Brian Edgar Looker	PG4763USW	8757

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EXAMINER
ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,339	Applicant(s) LOOKER ET AL.	
	Examiner James H. Alstrum-Acevedo	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11 and 15-16 is/are allowed.
- 6) ☒ Claim(s) 13 and 20-23 is/are rejected.
- 7) ☒ Claim(s) 7 and 12-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/16/06; 9/1/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 and 20-23 are pending. Applicants cancelled claims 17-19. Applicants amended claims 1-16 and 20. Claims 21-23 are new.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

None of the references listed on the IDS submitted on September 1, 2004 were considered, because these foreign patent documents were not provided, with the exception of PCT document, PCT/92/00061, which was a duplicate reference.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims 7 and 12-14 are objected to because of the following informalities: (1) the word "claim" in line 2 of claim 7 should be plural (i.e. "claims"); (2) the indefinite article, "a," should be inserted in line 2 between the words "comprises" and "particulate"; (3) a space should be inserted between all numerical values and corresponding units of measurement thereof in claims 12 (line 3) and 13 (line 2). Appropriate correction is required.

The use of the trademark BIOTAGE® ([0196]) and BOND ELUT® ([0197]) have been noted in this application. Trademarks should be capitalized wherever these appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of asthma, COPD, rhinitis, does not reasonably provide enablement for all respiratory diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

An analysis based upon the Wands factors is set forth below.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993),. See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re*

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Fisher 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* (230 USPQ 546, 547 (Bd Pat App Int 1986)). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Breadth of Claims

Applicants' claims are broad. Applicants claim the treatment of any respiratory disease by administration of a pharmaceutical formulation comprising (i) any particulate medicament, (ii) a fluorocarbon or hydrogen-containing chlorofluorocarbon propellant, and (iii) a compound according to claim 1. Applicants specification does not define medicament and states that suitable medicaments including anti-allergics, anti-histamines, anti-inflammatories, analgesics, anginal preparations, anti-cholinergics, etc.

Nature of the invention/State of the Prior Art

The instant invention is drawn to compositions having phosphatidyl choline derivative surfactant compounds represented by formula (I) in claim 1, as well a pharmaceutical aerosol formulations and metered dose inhalers comprising said surfactant and methods of treatment involving administration of said formulations.

The prior art recognizes a plethora of respiratory diseases that are not treated using any of the specific medicaments or drug classes disclosed in Applicants' specification. For example, none of the drug classes mentioned in Applicants' specification are indicated for the treatment of

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bronchopulmonary dysplasia, Langerhan's cell granulomatosis, viral respiratory infections (e.g. RSV, influenza, bird flu), pulmonary embolism, etc. (See (1) Lacy, C.; Armstrong, L. L.; Lipsy, R. J.; Lance, L. L. Drug Information Handbook, Lexi-Comp, Inc.: Cleveland, 1999, pp 32-34, 112-114, 253-254, 259-260, 262-263, 319-321, 547-549, 781-785 or (2) MERCK Manual home edition online articles entitled: "Bronchopulmonary Dysplasia (BPD); "Langerhan's Cell Granulomatosis"; "Respiratory Tract Infections"; "Pulmonary Embolism(PE)", and "Lung Cancer"). The prior art, however, does recognize that several of Applicants' disclosed suitable medicaments (e.g. anti-cholinergics, bronchodilators, anti-inflammatories) are suitable in the treatment of asthma.

Level of One of Ordinary Skill & Predictability/Unpredictability in the Art

The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g. M.D., Ph.D., Pharm. D. or combinations thereof). There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970).

Guidance/Working Examples

The instant specification only mentions on pages 5 that formulations of Applicants' invention may be used to treat COPD and rhinitis. No other respiratory diseases are specifically taught as being treatable using Applicants' formulations. The specification is devoid of working examples related to the treatment of any disease. The specification does not contain data for the treatment of any disease. Thus, it would represent an undue serious burden for an ordinary

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skilled artisan to obtain suitable formulations for the treatment of every possible respiratory disease known and unknown to science per Applicants' disclosure.

Therefore, the Examiner concludes that the instant specification is not enabled to treat any respiratory disease. The instant specification is only enabled to treat the following respiratory diseases: COPD, asthma, and rhinitis.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 13, 20, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitations "the range" and "the amount" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 is indefinite because it refers to an activated derivative on lines 30, 36-37, and 44. The terms derivative or activated derivative are not defined in the specification. The 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield, Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." For example, carbon dioxide could theoretically be derived from the combustion of the carboxylic acid of formula (III)¹ in claim 20. Therefore, the definition of derivative in the Merriam-Webster Collegiate Dictionary does not shed light on what Applicants' intended for the meaning of a derivative or activated derivative, as used throughout claim 20.

The remaining claims are rejected for depending upon a rejected claim.

Allowable Subject Matter

Claims 1-11 and 15-16 are allowed. A search of the prior art did not uncover the compound of formula (I).

Other Matter

The Examiner respectfully requests that Applicants amend the instant specification to properly identify the parentage of the instant application as well as the foreign priority based upon UK 0205327.0.

Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,413,543 is cited because it teaches a structurally similar, albeit different phosphatidyl choline compound as claimed in claim 1 and claims dependent therefrom of the instant application.

The specification and claims 7 and 12-14 are objected. Claims 13 and 20-23 are rejected. Claims 1-11 and 15-16 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571)

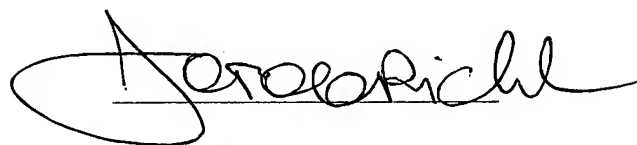
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272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Patent Examiner
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A handwritten signature in black ink, appearing to read 'Johann Richter', written over a horizontal line.

Johann Richter, Ph. D., Esq.
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